



HPW

PATENT
1377-0188P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: John K. COLLINS et al. Conf.: 1455
Appl. No.: 10/603,865 Group: 1651
Filed: June 26, 2003 Examiner: I. Marx
For: PROBIOTIC STRAINS FROM LACTOBACILLUS SALIVARIUS
AND ANTIMICROBIAL AGENTS OBTAINED THEREFROM

INFORMATION DISCLOSURE STATEMENT
(SUBMISSION AFTER FILING OF AN APPLICATION
BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE
OR CONCURRENTLY WITH A RULE 1.114 RCE APPLICATION)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

July 28, 2004

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby submit an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-1449(s), attached hereto.

II. COPIES (check at least one box)

- a. ☒ This application was filed before June 30, 2003. **Copies of all reference cited on the attached PTO-1449 forms have been submitted in an IDS filed concurrently herewith in copending Application No. 10/606,114. If the USPTO desires additional copies of each of the references, the Examiner is respectfully requested to contact the undersigned.**
- b. ☐ This application was filed on or after June 30, 2003. Accordingly, copies of cited U.S. patents and patent application publications therefore are not included. Copies of foreign patent documents and non-patent literature are included.

- c. ☐ Some or all of the documents listed on the PTO-1449 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

III. CONCISE EXPLANATION OF THE RELEVANCE
(check at least one box)

- a. ☒ **DOCUMENTS IN THE ENGLISH LANGUAGE**

The patents, publications, or other information listed on the attached PTO 1449 are in the English language and therefore, do not require a statement of relevancy.

- b. ☐ **DOCUMENTS NOT IN THE ENGLISH LANGUAGE**

A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

- c. ☐ **ENGLISH LANGUAGE SEARCH REPORT**

An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

- d. ☒ **OTHER**

The following additional information is provided for the Examiner's consideration.

U.S. Patent 6,077,504 corresponds to WO 98/00035.

An English Abstract of JP 9-241173A is provided. An English Abstract is also provided for the Lait (1993) 73, 241-247, reference.

FEEs

IV. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b):
(check one box)

- a. ☐ within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. (This section is not to be used with RCE's.)
- b. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.
- c. ☐ concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- d. ☒ before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required.
In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

- a. ☐ No statement; therefore, a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).
or
- b. ☐ See the statement below. No fee is required.

VI. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby states that

- a. ☐ each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or
- b. ☐ each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- c. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.
- d. ☐ Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VII. PAYMENT OF FEES (check one box)

- ☐ A check in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p) is enclosed for the above-identified fee.
- ☐ Please charge Deposit Account No. 02-2448 in the amount required by 37 C.F.R. § 1.17(p) for the above-indicated fee. A triplicate copy of this paper is attached.
- ☒ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By _____
MaryAnne Armstrong, #40,069

MAA/ETP/kas
1377-0188P

P.O. Box 747
Falls Church, VA 22040-0747
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Attachment(s): ☒ PTO-1449
☐ Documents
☐ Foreign Search Report
☐ Fee
☐ Other:

(Rev. 05/14/2004)



Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)	ATTY. DOCKET NO. 1377-0188P	APPLICATION NO. 10/603,865
	APPLICANT John K. COLLINS et al.	
	FILING DATE June 26, 2003	GROUP 1651

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	Kind	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	US 4,347,240		1982-08-31	Mutai et al.			
	US 5,032,399		1991-07-16	Gorbach et al.			
	US 6,132,710		2000-10-17	Panigrahi et al.			

FOREIGN PATENT DOCUMENTS

	Office	DOCUMENT NUMBER	Kind	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
								YES	NO
	WO	90/01335	A1	1990-02-22	PCT				
	WO	90/09398	A1	1990-08-23	PCT				
	WO	97/35596	A1	1997-10-02	PCT				
	WO	98/00035	A1	1998-01-08	PCT				
	JP	9-241173	A	1997-09-16	JAPAN			w/abs.	

OTHER DOCUMENTS

(Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.)

	Gardiner et al., <i>Applied and Environment Microbiology</i> , Vol. 64, No. 6, pp. 2192-2199 (June 1998)
	J. K. Collins et al., <i>Ini. Dairy Journal</i> , Vol. 8, pp. 487-490, (1998)
	William P. Charteris et al., <i>International Journal of Food Microbiology</i> , Vol. 35, pp. 1-27, (1997)
	Seppo Salminen et al., <i>International Journal of Food Microbiology</i> , Vol. 44, pp. 93-106, (1998)
	C. Stanton et al., <i>Int. Dairy Journal</i> , Vol. 8, pp. 491-496 (1998)
	Collins et al., Demonstration of the Nutritional Functionality of Probiotic Foods FAIR-CT96-1028, Functional Food Research In Europe, 3 rd Workshop, Haikko Manor, Finland, pp. 40-41 (October 1-2, 1998)
	Morrisey et al., "Selection of a probiotic strain to modify human gut flora and a controlled trial of delivery and efficacy," <i>Irish Journal of Medical Science</i> , Vol. 167, Supplement 8 (1998); Abstract from meeting of Irish Society for Gastroenterology, June 12-13, 1998
	Sarem-Damerdjji et al., <i>FEMS Microbiology Letters</i> , Vol. 131, pp. 133-137 (1995)
	O'Sullivan et al., The Human Gut as a Source of Probiotic Bacteria - Myth or Reality?, <i>Irish Journal of Medical Science</i> , Vol. 162, Suppl. 11, p. 25, National Scientific Medical Meeting, March 18-20, 1993

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	US 6,077,504	A	2000-06-20	Cavaliere ved. Vesley et al.			
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	Bouhnik, <i>Lait</i> , Vol.73, pp. 241-247, (1993) (Abstract provided)						
	Vaughan et al., <i>Journal of Applied Bacteriology</i> , Vol. 76, pp. 118-123, (1994)						
	Prof. Kevin Collins, VTT Symposium 167, 1 st Workshop, FAIR CT96-1028, Probdemo, Probiotic Lactobacilli - Towards Defining Selection and Functional Criteria, p. 27 (1996)						
	Collins et al., J. Roy Soc. Med International Congress and Symposium Series 219 - Roy. Society of Medicine Press, 219:13-17 (1996)						
	Daly et al., "Biotechnology of lactic acid bacteria with special reference to bacteriophage resistance" (in Lactic Acid Bacteria: Genetics, Metabolism and Applications), Antonie van Leeuwenhoek, Vol. 70, pp. 99-110 (1996)						
	Huis In't Veld et al., International Congress and Symposium Series 219, pp. 27-36, (1996)						
	Kawakami et al., <i>The Journal of Immunology</i> , Vol. 132, No. 5, pp. 2578-2581 (May 1984)						
	Rowland, Toxicology of the Colon: Role of the Intestinal Microflora, In: Gibson G.R. (ed.) <i>Human Colonic bacteria: Role in nutrition, physiology and pathology</i> , 1995, pp. 155-172, Boca Raton CRC Press						
	Legrand-Defretina et al., <i>LIPIDS</i> , Vol. 26, No. 8, pp. 578-583, (1991)						
	Oksanen et al., <i>Annals of Medicine</i> , Vol. 22, pp. 53-56, (1990)						
	Walker, "New Strategies for Mucosal Vaccination," <i>Vaccine</i> , Vol. 12, pp. 387-400 (1994)						
	Isolauri et al., <i>Digestive Diseases and Sciences</i> , Vol. 39, No. 12, pp. 2595-2600 (December 1994)						
	Gibson, <i>Br. Journal of Nutrition</i> , Vol. 80, Suppl. 2, pp. S209-S212 (1998)						
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	Groot, <i>The Veterinary Quarterly</i> , Vol. 20, Suppl. 3, pp. S45-S49, (June 1998)						
	Kato et al., <i>Life Sciences</i> , Vol. 63, No. 8, pp. 635-644, (1998)						
	Raychaudhuri et al., "Fully Mobilizing Host Defense: Building Better Vaccines," <i>Nat biotechnol.</i> , 16:1025-1031 (1998)						
	Steidler et al., <i>Infection and Immunity</i> , Vol. 66, No. 7, pp. 3183-3189 (July 1998)						
	McFarland et al., <i>Anaerobe</i> , Vol. 3, pp. 73-78 (1997)						
	Henderson et al., (Cytokines, homeostasis, networks and disease) In: <i>Bacteria Cytokine Interactions In Health and Disease</i> , Portland Press, pp. 79-132 (1998)						
	Tagg et al., <i>Bacteriological Reviews</i> , Vol. 40, No., 3, pp. 722-756 (Sept. 1976)						
	Collins et al., "Demonstration of probiotic function in a double blind placebo controlled clinical trials in adults," 3 rd Workshop, Demonstration of the Nutritional Functionality of Probiotic Foods, FAIR-CT96-1028, Functional Food Research in Europe, Haikko Manor, Finland, pp. 40-41 (October 1-2, 1998)						
	Siitonen et al., <i>Ann. Med.</i> , Vol. 22, pp. 57-59 (1990)						
	Charteris et al., <i>Journal of Food Protection</i> , Vol. 61, No. 12, pp. 1636-1643 (1998)						
	Dekker et al., <i>Chromatographia</i> , Vol. 31, No. 11/12, pp. 549-553 (June, 1991)						
	O'Sullivan et al., "Isolation and selection of normal gut microflora for use as prophylactic probiotic agents," <i>Irish Journal of Medical Science</i> , Irish Society of Gastroenterology, p. 420 (Proceedings of meeting held in Dublin, 7 th and 8 th June, 1991)						
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	Vaughan et al., <i>Journal of Applied Bacteriology</i> , Vol. 73, pp. 299-308 (1992)						
	Savage, D.C., Interaction between host and its microbes. In: <i>Microbial Ecology of the Gut</i> , Clark and Bauchop (eds), Academic Press, London, pp. 277-310 (1977)						
	Charteris et al., <i>Journal Applied Microbiology</i> , Vol. 84, pp. 759-768, (1998)						
	Mattila-Sandholm, VTT Symposium 173, Novel Methods for Probiotic Research, Technical Research Center of Finland, 2 nd Workshop, FAIR CT96-1028, Probdemo, pp. 11-15, Espoo, Finland (1997)						
	Lucey et al., <i>Food Science and Technology Today</i> , Vol. 11, No. 4, pp. 230-233, (1997)						
	Shanahan et al., "Grand Entry for Listeria," <i>Gastroenterology</i> , Vol. 112, No. 3., pp. 1045-1046 (1997)						
	Thornton et al., "Determination of stringent criteria essential to the survival/growth/colonization of probiotic human intestinal tract bacteria," Book of Abstracts, European Commission Biotechnology and Fair Programmes, Conference on Lactic Acid Bacteria, Cork, Ireland (October 22-26, 1995)						
	Collins, "Selection of Probiotic Strains and Potential Therapeutic Applications," Book of Abstracts, European Commission Biotechnology and Fair Programmes, Conference on Lactic Acid Bacteria, Cork, Ireland, p. 3 (October 22-26, 1995)						
	Thornton et al., "The production of a novel anti-microbial substance by human intestinal microflora," <i>Irish Journal of Medical Science</i> , Supplement with Irish Society of Gastroenterology, Proceedings of Poster Section of Meeting held in Cork, pp. 603-604 (June 3-4, 1994)						
	O'Sullivan et al., "Probiotic bacteria in the human gastro intestinal tract (Myth or Reality)," <i>Irish Journal of Medical Science</i> , Supplement with Proceedings with the Irish Society of Gastroenterology Meeting, Winter Meeting held December 4-5, 1992 in Beaumont Hospital, Dublin						
	Chauviere et al., <i>Journal of General Microbiology</i> , Vol. 138, pp. 1689-1696 (1992)						
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	Thornton et al., <i>Gasterentology</i> , Vol. 108, No. 4, p.A928 (April 1995)						
	O'Halloran et al., <i>International Dairy Journal</i> , Vol. 8, No. 5/6, (published October 16, 1998); Abstract from meeting held in Cork, Ireland 30 Sept-2 Oct 1997.						
	Flynn et al., <i>International Dairy Journal</i> , Vol. 8, No. 5/6, (published October 16, 1998); Abstract from meeting held in Cork, Ireland 30 Sept-2 Oct 1997.						
	Gardiner et al., <i>International Dairy Journal</i> , Vol. 8, No. 5/6, p. 597 (published October 16, 1998); Abstract from meeting held in Cork, Ireland 30 Sept-2 Oct 1997.						
	Murphy et al., <i>International Dairy Journal</i> , Vol. 8, No. 5/6, (published October 16, 1998); Abstract from meeting held in Cork, Ireland 30 Sept-2 Oct 1997.						
	Thornton et al., "Human intestinal probiotic bacteria: Production of anti-microbial factors," <i>Irish Journal of Medical Science</i> , Supplement with Proceedings of the Irish Society of Gastroenterology, pp.362-363, Proceedings of Meeting Held in Craigavon on May 28-29 (1993)						
	Thornton et al., "Bile acid tolerance and deconjugating activity of lactobility," <i>Irish Journal of Medical Science</i> , Supplement with Proceedings of the Irish Society of Gastroenterology, Proceedings of Winter Meeting, Dublin, November 25-26, 1994, p. 578						
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